JAN 25 2012

510(k) Summary of Safety and Effectiveness

Date Prepared: December 22, 2011

Submitter:
Medtronic, Inc.
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Device Name and Classification:

Trade Name:	Tubing, Connectors and Accessories with Balance™ Biosurface
Common Name:	Cardiopulmonary bypass adapter tubing, connector, stopcock, manifold or fitting
Regulation Number:	21 CFR 870.4290
Product Code:	DWF and DTL
Product Code:	Class II

Predicate Devices

Intersept Custom Tubing Pack (K800178)
Bio-Medicus Tubing Connectors (K883956)
Signature Custom Tubing Pack (K924529)
Trillium Coated Tubing and Connectors (K012538)
Affinity Pixie™ Arterial Filter with Balance™ Biosurface (K100646)

Device Description

Tubing, Connectors, and Accessories with Balance™ Biosurface are used in cardiopulmonary bypass for connecting the primary devices of the bypass circuit. The

functionality and intended use of these devices are the same as those for the coated (Trillium® Biosurface) and uncoated tubing, connectors, and accessories that are FDA cleared. Balance™ Biosurface has been previously FDA cleared (K100646) and is commercially available. Balance™ Biosurface is a non-leaching biocompatible surface that reduces platelet adhesion and activation and preserves platelet function.

Intended Use

There is no change to the indication for use for these devices/components.

The Medtronic Custom Perfusion System is indicated for use in the extracorporeal circuit during cardiopulmonary bypass surgery procedures.

Comparison to Predicate Devices

A comparison of the modified product and the currently marketed tubing, connectors, and accessories with Trillium® Biosurface (K012538), Intersept Custom Tubing Pack (K800178), Bio-Medicus Tubing Connectors (K883956), and Signature Custom Tubing Pack (K924529) indicates the following similarities to the product which received 510(k) clearance:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features (with the exception that Balance™ Biosurface will not contain heparin in the coating)
- Same base materials prior to coating
- Same shelf life

A comparison of the modified product and the currently marketed Affinity Pixie™ Arterial Filter with Balance™ Biosurface (K100646) indicates the following similarities to the product which received 510(k) clearance:

- Same Balance™ Biosurface coating

Summary of Performance Data

Verification and validation testing has demonstrated that the tubing, connectors, and accessories with Balance™ Biosurface are substantially equivalent to the predicates. The following performance tests were conducted:

Verification/Validation	Results
Balance™ Biosurface coverage	Pass
Balance™ Biosurface leaching	Pass
Hemolysis	Pass
White Blood Cell (WBC) Retention	Pass
Platelets Retention/ Platelet Activation	Pass
Kallikrein Generation	Pass
Tubing kink resistance	Pass

Pressure integrity	Pass
Pressure decay	Pass
Tubing pull force	Pass
No tubing pull off during static force	Pass
Tubing Life	Pass
Tubing Spallation	Pass
Biocompatibility Assessment	Pass – no impact to biocompatibility
Packaging and Sterilization Assessment	Pass – no impact to packaging and sterilization
Shelf-Life Verification	Pass

Conclusion

Medtronic has demonstrated that the tubing, connectors, and accessories with Balance™ Biosurface for use in custom perfusion system are substantially equivalent to the predicate devices based upon design, test results and indications for use. The fundamental scientific principle, labeling and the intended use are unchanged as a result of these device modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Medtronic, Inc.
c/o Mr. Kevin T. Lam
Senior Regulatory Affairs Specialist
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428

Re: K113845
Trade/Device Name: Tubing, Connectors, and Accessories with Balance™ Biosurface
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting
Regulatory Class: Class II
Product Code: DTL
Dated: December 22, 2011
Received: December 28, 2011

Dear Mr. Lam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address. http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113845

Indications for Use Statement

510(k) Number (if known): K113845

Device Name: Tubing, Connectors, and Accessories with Balance™ Biosurface

Indications for Use:

This product is indicated for use in the extracorporeal circuit during cardiopulmonary bypass surgery procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M J Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113845